

In view of the foregoing, Applicant requests the withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 U.S.C. § 101

The Office rejects claim 3 as being an improper and nonstatutory process claim for reciting a use but failing to positively recite any method/process steps. Applicant's cancellation of claim 3 renders moot the rejection.

In view of the foregoing, Applicant requests the withdrawal of the rejection under 35 U.S.C. § 101.

Claim Rejections - 35 U.S.C. § 102

The Office rejects claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by EP 194 838 B1 to Fukui et al. Applicant's cancellation of claims 1 and 2 renders moot this rejection and Applicant respectfully requests its withdrawal.

Claim Rejections - 35 U.S.C. § 103

The Office rejects claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Yasuda et al. (*The Journal of Urology*, Vol. 156, p. 1125-1130, 1996) in view of U.S. Patent No. 6,071,882, to Engel et al. The Office states that Yasuda et al. discloses that alpha blockers are effective at improving urinary flow rates and residual urine in cases of voiding dysfunction *caused by benign prostatic hyperplasia (BPH)*, and that Engel et al. teaches that tamsulosin is an alpha blocker. The Office asserts that it would have been obvious to use tamsulosin "to improve urinary flow rates and residual urine in

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cases of voiding dysfunction caused by BNP¹, because Yasuda et al. teach that alpha blockers are successful for this very purpose.”

Initially, Applicant notes that claim 4 is directed to the therapy of voiding dysfunction associated with *neurogenic bladder*, not with BPH. The specification clearly distinguishes the two disease states causing voiding dysfunction:

There are various diseases which cause the urinary dysfunction and main ones are classified into (1) neurogenic bladder caused by cerebrospinal disease, cerebrovascular accident, diabetes mellitus, peripheral nervous disturbance, etc., [and] (2) organic lower urinary tract obstruction such as benign prostatic hyperplasia and urethral stricture . . .”

(Page 1, lines 17-22.) The next two paragraphs of the application further detail the differences:

[I]n urinary dysfunction associated with *prostatic hyperplasia*, the urinary dysfunction is generated by both urethral stricture (mechanical obstruction) caused by compression of enlarged prostate and over-shrinkage (functional obstruction) of smooth muscle of prostate accompanied by an increase in $\alpha 1$ receptors in the enlarged prostate [citation omitted]. On the other hand, *neurogenic bladder* is a general term for abnormal urination caused by disorder of sympathetic never [sic, nerve], parasympathetic nerve, etc. controlling the action of bladder and urethra but it does not stand for localizing and systematic diseases [citation omitted].

(Page 2, lines 6-18, emphasis added.) Clearly, voiding dysfunction resulting from BPH is a distinctly different medical condition from the dysfunction caused by neurogenic bladder. Thus, while Yasuda et al. may state that alpha-blockers are effective in treating voiding dysfunction caused by BPH, it does not teach or suggest that alpha-blockers are effective in treating dysfunction caused by neurogenic bladder.

¹ It is not clear what the Office means by “BNP.” Applicant assumes that “BPH” was intended, because the Office asserts that Yasuda et al. discloses that alpha-blockers

Additionally, the very purpose of the Yasuda et al. study was to test whether urapidil, an alpha-blocker, could be used to treat neurogenic bladder, *knowing that it was effective in treating voiding dysfunction caused by BPH*. (See Yasuda et al., page 1125, right column, first paragraph.) Yasuda et al. sought to test the effectiveness of urapidil on voiding dysfunction caused by neurogenic bladder, as *separate from* BPH or other obstruction. Patients with BPH were actually excluded from the study. (Yasuda et al., paragraph spanning pages 1125-1126.) Thus, Yasuda et al., persons skilled in the art, chose to test the efficacy of urapidil on neurogenic bladder, even though they knew that it was also effective on voiding dysfunction caused by BPH. This published study is evidence that persons skilled in the art would not expect compounds useful in treating voiding dysfunction caused by BPH to *necessarily* be useful in treating dysfunction caused by neurogenic bladder.

If anything, Yasuda et al. seems to suggest that alpha-blockers, as a whole, were not known to be useful in treating voiding dysfunction due to neurogenic bladder. For example, Yasuda et al. state that alpha-blockers were demonstrated to be superior in treating multiple sclerosis (a cause of neurogenic bladder), without demonstrating significant improvement in urinary symptom score. (See Yasuda et al., page 1125, citation to study by O'Riordan et al.) Other studies of alpha-blockers in neurogenic bladder also failed to demonstrate significant improvement in the parameters, as measured by routine urodynamic studies. (See Yasuda et al., page 1125, left column, citation to reference number 8.) Thus, while Yasuda et al. may suggest that some alpha-blockers are effective in treating voiding dysfunction *caused by BPH*, it does not

are useful in voiding dysfunction caused by BPH.

appear to suggest a similar effectiveness in treating dysfunction caused by neurogenic bladder.

In conclusion, the Office has at most established motivation for using tamsulosin in treating voiding dysfunction caused by benign prostatic hypertrophy, when Applicant's claims are directed to an entirely different use, neurogenic bladder. Applicant respectfully submits that the Office has failed to make a prima facie case of obviousness of claim 4, and that the claim is nonobvious in light of the cited art.

In view of the foregoing amendment and remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claim.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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APPENDIX TO AMENDMENT

The application is amended as follows:

In the Specification

Page 2, paragraph beginning at line 13, is amended as follows:

On the other hand, *neurogenic bladder* is a general term for abnormal urination caused by disorder of sympathetic [never] nerve, parasympathetic nerve, etc. controlling the action of bladder and urethra but it does not stand for localizing and systematic diseases (cf. "Hyojun Hinyoki Kagaku", the fifth edition, published in 1998).

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